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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,906	11/30/2000	Lisa McKerracher	06447-003-US-02	9776

7590 01/21/2004

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/725,906	MCKERRACHER, LISA	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *3,6 and 8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *07 January 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No. 4/12/02, 12/6/02
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please disregard the previous office action, dated 24 June 2003 as it was sent before receipt of the Applicant's response concerning Sequence Rules violations. The office action of 24 June 2003 is hereby VACATED. Applicant is relieved of the requirement to respond to the previous Office Action (24 June 2003).

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement, sent 5 April 2002 and the Supplemental Information Disclosure Statement, sent 6 December 2002, have been entered into the record. The Amendment sent 7 January 2003 has not been entered. Applicant elected Invention II (Claims 1, 2, 3, 5 and 6) in the response filed 22 August 2002. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4 and 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, 3, 5 and 6 are under examination in the current application.

Informalities

Figures

Figure 9 is objected to because it is not clear from the figure or from the specification what the components of the algorithm are, and such information is crucial to an understanding of the claimed invention. More specifically, it is not clear what is contained in each square of the diagram (e.g., they are "blank"). Corrections will be

required in the event there are allowable claims, however the Applicant is cautioned about adding *new matter* to the Specification.

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not accompanied by the required reference to the relevant sequence identifier (i.e., SEQ ID NO:). This occurs throughout the disclosure, but see for examples: the nucleotide sequences listed on pages 41 and 42.

Appropriate correction is required.

Claim Rejections/Objections

Claim rejections-

35 *USC § 112, first paragraph-scope of enablement*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1, 2, 3, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an axon-elongation stimulation kit comprising *C3* at tested concentrations (e.g., corresponding to a final *in situ* concentration of 25-

50μg/ml), combined in a gel matrix with "fibrin sealant" (comprising fibrinogen concentrate, calcium chloride, thrombin and protease inhibitors), is not enabled for an axon-growth stimulation kit comprising two or more containers containing components *capable of forming a therapeutically acceptable matrix*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1, 2, 3, 5 and 6 are directed to an axon growth stimulation kit comprising a compartment or compartments for containing components capable once intermingled of forming a flowable carrier component and a second container for a therapeutically active agent for facilitating axon growth at a site of injury in vivo. The scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The specification is not enabled for the full scope of the claimed apparatus, wherein the apparatus comprises compartments containing components "capable once intermingled of forming a flowable carrier component and a second container with a therapeutically active agent for facilitating axon growth at a site of injury" with the assurance that the apparatus claimed can be made and used without undue experimentation and with the assurance that it would have the desired properties. There are no examples of what specific compounds would be used in the apparatus or fall within the range of those that would be included and still be useful for facilitating axon growth. Furthermore, the field of neural development is not well-established in terms of clearly defining the specific series of compounds and steps involved in causing axon

elongation in vivo. For example, many classes of compounds, including cytoskeletal proteins, growth factors and growth-inhibiting factors are involved in *in vivo* guidance of each axon, at least during development (Zigmond, M.J., editor, 1999, Fundamental Neuroscience, Academic Press, pages 526-543). Still less is known about axon elongation after injury in adult animals, but since central nervous system axon growth is rarely seen after injury in adults, it can be assumed that there exist barriers to such growth.

The specification discloses enabled utilities for an axon-elongation stimulation kit comprising *C3* at tested concentrations (e.g., corresponding to a final *in situ* concentration of 25-50μg/ml), combined in a gel matrix with "fibrin sealant" (comprising fibrinogen concentrate, calcium chloride, thrombin and protease inhibitors). However, the instant claims read on an apparatus with multiple compartments comprising any combination of peptide or non-peptide compounds that are mixed with any thixotrope to form a matrix for in vivo application.

Due to the large quantity of experimentation required to determine how to use the apparatus described to stimulate axon growth, the lack of direction or guidance in the specification regarding same - e.g., the lack of guidance regarding use of components other than *C3* combined with the "fibrin sealant" matrix, the lack of working examples to all variants of the claimed components, the state of the art showing the many types of compounds that can cause axon elongation, the unpredictability of function of most injected compounds in terms of causing axon elongation, and the breadth of the claims which embrace innumerable compounds defined only vaguely and only in terms of

function- undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

35 USC § 112, first paragraph – Written Description.

Claims 1, 2, 3, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 3, 5 and 6 are directed to an axon growth stimulation kit comprising a compartment or compartments for containing components capable of forming a flowable carrier component and a second container for a therapeutically active agent for facilitating axon growth at a site of injury in vivo.

The specification teaches use of *C3* and "fibrin sealant" in the axon growth stimulation kit. However, the specification does not teach functional or structural characteristics of the compound or compounds used in the kit. The description of several compounds described only as capable of stimulating axon growth or of forming a flowable matrix is not adequate written description of an entire genus of functionally equivalent compounds that stimulate axon growth or form a flowable matrix.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does

not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the C3 and "fibrin sealant" compounds referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds, and therefore, would not know how to make or use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or using. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. *The product itself is required.* See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the apparatus comprising *C3* and "fibrin sealant," but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph, indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 2, 3, 5 and 6, the phrase "axon *growth*" renders the claims indefinite because the term "growth" is too vague. "Growth" has been used in the literature to describe increases in volume, height and number and has been applied when referring to cells, tissues and whole organisms. It is suggested that the phrase "axon *growth*" be replaced by a more specific phrase that accurately describes the process of axonal elongation. See MPEP § 2173.05(d).

35 USC § 102- Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 USC 102(b), as being anticipated by Redl, et al (US Patent 4,631,055 23 December 1986). Redl, et al teach a two-compartment apparatus for dispensing a composition for in vivo use. It should be kept in mind that phrases used in the claims of the instant Application, such as: "for containing a therapeutically-acceptable matrix" and "facilitating axon growth at the lesion site" are intended-use phrases and are not givem patentable weight in regards to prior inventions.

The instant Claims makes no mention of properties that distinguish the claimed apparatus from those disclosed in the US Patent 4,631,055 23 (Redl, 1986) such as, for example: exact compositions of injected proteins and the concentrations of the ligand proteins listed in the examples of the instant Specification (e.g., "fibrin sealant" with C3 at 25-50μg/ml).

Conclusion: Claims 1, 2, 3, 5 and 6 are rejected for the reasons listed above.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
10/13/03

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER